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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,135	10/17/2003	George P. Teitelbaum	VLINK.002DV2	2028

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/07/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/07/2007.

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jcartee@kmob.com
eOAPilot@kmob.com

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Office Action Summary	Application No. 10/688,135	Applicant(s) TEITELBAUM, GEORGE P.	
	Examiner Jerry Cumberledge	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,12 and 36-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11,12 and 36-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/17/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 11 and 12 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

Claims 37, 38, 39, 40, 47, 48, 49 and 50 are objected to because of the following informalities:

Claims 37, 38, 39, 40, 47, 48, 49 and 50 should all end with a period.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44-53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44, lines 7-8 recites "...at least two openings that extend through the central portion of the generally traverse to a longitudinal axis of the directing sheath intersecting the longitudinal lumen..." It is unclear what this statement means. It appears that the phrase --directing sheath--should be inserted between "central portion of the" and "generally traverse to a" and that "traverse"

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should be replaced with --transverse--. This is the interpretation that will be used for examination purposes.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11, 36-41, 43, 44, 46-51 and 53 are rejected under 35

U.S.C. 102(e) as being anticipated by Davey (US Pub. 2005/0027257 A1).

Davey discloses a directing sheath (Fig. 13, ref. 10) comprising: a proximal portion (Fig. 13 below) with a proximal end (Fig. 13 below); a distal portion (Fig. 13 below) with a distal end (Fig. 13 below); a central portion (Fig. 13 below) between the proximal portion and the distal portion comprising at least two openings (Fig. 13 below) that extend generally traverse to a longitudinal axis of the directing sheath; and a lumen (paragraph 0042, first sentence, i.e. the passageway) extending through the directing sheath from the proximal end to distal end generally along the longitudinal axis of the directing sheath (paragraph 0042, first sentence) and intersecting the at least two openings (since the

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openings and lumen converge at the top of the device, near ref. 14, as best seen in Fig. 10); where the directing sheath is scored along its longitudinal axis (Fig. 13, ref. 44) (paragraph 0045, lines 1-8) to allow the directing sheath to be split into two separate halves and dividing the lumen by peeling the directing sheath apart at either its proximal end or its distal end or both along the scoring (paragraph 0058, lines 5-11). The lumen is configured to receive a guidewire. The directing sheath is scored completely through a sheath wall of the directing sheath, once the device has been completely separated along ref. 44. The directing sheath is scored completely through a sheath wall of the directing sheath along two opposing lines, once the device has been completely separated along ref 44. The directing sheath is scored partially through a sheath wall of the directing sheath (column 0045, lines 1-8). The directing sheath is scored partially through a sheath wall of the directing sheath along two opposing lines (paragraph 0045, lines 1-8). The directing sheath comprises a biocompatible polymer (paragraph 0052). The at least two openings (Fig. 13 below) are sized substantially the same as a portal on a bone screw.

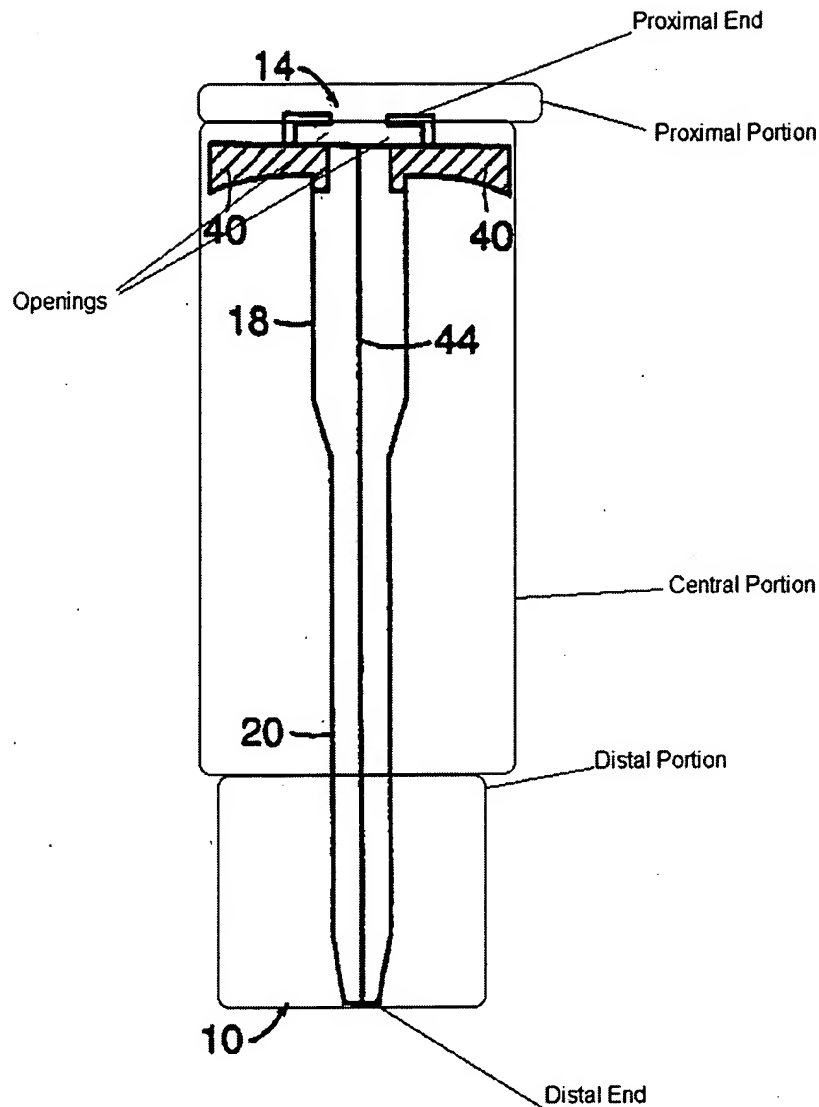
Davey discloses a directing sheath comprising: a body (Fig. 13, ref. 10) extending along a longitudinal axis (the axis extending from near ref. 14 to near ref. 10), the body having a proximal portion (Fig. 13 below) with a proximal end (Fig. 13 below); a distal portion (Fig. 13 below) with a distal end (Fig. 13 below), and a central portion (Fig. 13 below) between the proximal portion and the distal portion; a longitudinal lumen (paragraph 0042, first sentence, i.e. the passageway) extending through the directing sheath from the proximal end to

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distal end generally (paragraph 0042, first sentence); at least two openings (Fig. 13 below) that extend through the central portion (Fig. 13 below) of the directing sheath generally transverse to a longitudinal axis of the directing sheath (Fig. 13 below) intersecting the longitudinal lumen (Fig. 13 below); and where the directing sheath is scored along its longitudinal axis (Fig. 13, ref. 44) (paragraph 0045, lines 1-8) to allow the directing sheath to be split into two separate parts and dividing the longitudinal lumen by peeling the directing sheath apart at either its proximal end or its distal end or both along the scoring (paragraph 0058, lines 5-11). With regards to the phrase "...at least two openings that extend through the central portion ...", it is noted that the examiner is considering the openings to be extending through the central portion, but not entirely through (e.g. partially through). The lumen is configured to receive a guidewire. The directing sheath is scored completely through a sheath wall of the directing sheath, once the directing sheath has been completely separated along ref. 44. The directing sheath is scored completely through a sheath wall of the directing sheath along two opposing lines, once the device has been completely separated along ref. 44. The directing sheath is scored partially through a sheath wall of the directing sheath (paragraph 0045, lines 1-8). The directing sheath is scored partially through a sheath wall of the directing sheath along two opposing lines (paragraph 0045, lines 1-8). The directing sheath comprises a biocompatible polymer (paragraph 0052). The at least two openings (Fig. 13 below) are sized substantially the same as a portal on a bone screw

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With regards to statements of intended use and other functional statements (e.g. ...configured to receive a guidewire...), they do not impose any structural limitations on the claims distinguishable over the device of Davey, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).



Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been

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obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 42, 45 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davey (US Pub. 2005/0027257 A1) in view of Nissenbaum et al (US Pat. 3,155,091).

Davey discloses the claimed invention except for the directing sheath comprising a radiopaque filament running the longitudinal length of the directing sheath from the proximal end to the distal end and passing around each opening in the central portion.

Nissenbaum et al. disclose a radiopaque filament (Fig. 2, ref 11) (column 2, lines 5-8) running the length of a sheath (Fig. 2, ref. 10) from the proximal end to the distal end (column 2, lines 21-26), the radiopaque filament being used to determine the location of the sheath in the body (column 2, lines 58-63).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the directing sheath of Davey with a radiopaque filament running the length of a sheath from the proximal end to the distal end as taught by Nissenbaum, the radiopaque filament being used to determine the location of the sheath in the body (Nissenbaum et al., column 2, lines 58-63). With regards to the statement "...a radiopaque filament...passing around each opening in the central portion," since the filament of Nissenbaum would run from the proximal end of the directing sheath of Davey to the distal end of the sheath of Davey, and since the openings of Davey are between the proximal and distal ends, the filament would pass near each of the

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openings of Davey. The definition of "around", according to the Merriam-Webster Online Dictionary, is "near." Thus, if the references were combined as taught, the radiopaque filament of Nissenbaum would run the length of the directing sheath of Davey and the filament would pass around each of the openings of Davey.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

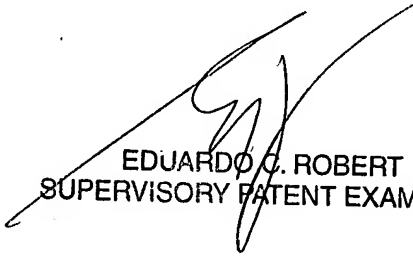
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER